EXHIBIT 1

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IN THE CIRCUIT COURT OF KANAWHA COUNTY, WEST VIRGINIA

IN RE: OPIOID LITIGATION **CIVIL ACTION NO. 21-C-9000 DISTRIBUTOR**

THIS DOCUMENT APPLIES TO ALL DISTRIBUTOR CASES

ORDER GRANTING CITY/COUNTY PLAINTIFFS' MOTION FOR PARTIAL SUMMARY JUDGMENT REGARDING DUTIES ARISING OUT OF THE CONTROLLED SUBSTANCES ACT

Pending before the Mass Litigation Panel ("Panel") is *City/County Plaintiffs' Motion for Partial Summary Judgment Regarding Duties Arising Out of the Controlled Substances Act* (Transaction ID 67623039). Having reviewed and considered the arguments raised in the Motion and Memorandum in Support, and Defendants' Memorandum of Law in Opposition (Transaction ID 67672567), the Panel finds that oral argument will not aid in the decisional process. Therefore, the Panel makes the following findings of fact and conclusions of law:

FINDINGS OF FACT AND CONCLUSIONS OF LAW

1. Plaintiffs are Cities and Counties of West Virginia, acting by and through counsel, that have sued Defendants AmerisourceBergen Drug Corporation, Cardinal Health, Inc., and McKesson Corporation (collectively "Defendants") in connection with their distribution of prescription opioids.

The Legal Standard

2. The Panel may enter an order granting partial summary judgment on all or part of a claim. Rule 56(a) of the West Virginia Rules of Civil Procedure provides that "[a] party seeking to recover upon a claim . . . may, at any time after the expiration of 30 days from the commencement of the action or after service of a motion for summary judgment by the adverse party, move with or without supporting affidavits for a summary judgment in the party's favor upon all ***or any part thereof***." W. Va. R. Civ. P. 56(a) (emphasis added). Summary judgment is

appropriately granted where "inquiry concerning the facts is not desirable to clarify the application of the law." *Greaser v. Hinkle*, 245 W. Va. 122, 857 S.E.2d 614, 618 (2021) (internal quotation marks and citation omitted).

3. It is thus appropriate to decide a pure question of law on a motion for summary judgment. *See City of Morgantown v. Nuzum Trucking Co.*, 237 W. Va. 226, 229, 786 S.E.2d 486, 489 (2016) ("The parties all agreed that issues raised in the summary judgment motions were purely legal and, therefore, were ripe for resolution by summary judgment."). This includes questions of statutory or regulatory interpretation, as well as the existence or content of a legal duty. *See, e.g., Pilgrim's Pride Corp. v. Morris*, 228 W. Va. 596, 599, 723 S.E.2d 642, 645 (2011) ("[I]nterpreting a statute or an administrative rule or regulation presents a purely legal question ....") (internal quotation marks and citation omitted); *Jackson v. Putnam Cnty. Bd. of Educ.*, 221W. Va. 170, 179, 653 S.E.2d 632, 641 (2007) ("[T]he question of the existence of a legal duty is a question of law appropriately resolved in a motion for summary judgment.").

Application of Standard

4. The Panel finds that the questions of what legal duties the federal Controlled Substances Act ("CSA"), 21 U.S.C. §§ 801 et seq., the West Virginia Uniform Controlled Substances Act ("WVCSA"), W. Va. Code §§ 60A-1-101 et seq., and the implementing regulations of the U.S. Drug Enforcement Administration ("DEA") and West Virginia Board of Pharmacy impose upon Defendants as distributors of controlled substances are both material to the Plaintiffs' claims for public nuisance, and disputed between the parties. These questions are therefore appropriately decided through the Plaintiffs' motion for partial summary judgment.

5. These statutes and regulations by their express terms require Defendants to maintain "effective controls against diversion" of controlled substances to unlawful use. 21

U.S.C. § 823(a)(1); W. Va. Code § 60A-3-303(a)(1); see also 21 C.F.R. § 1301.71(a) (all registrants "shall provide effective controls and procedures to guard against theft and diversion of controlled substances."); W. Va. C.S.R. § 15-2-5.1.1 (same).

6. As part of this duty, the federal and West Virginia regulations also expressly require Defendants to identify and report "suspicious orders of controlled substances" which are defined to "include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency." 21 C.F.R. § 1301.74(b); W. Va. C.S.R. § 15-2-5.5.3.

7. The primary dispute between the parties on this motion is whether the statutory and regulatory requirements to maintain effective controls against diversion have at all relevant times required Defendants to stop shipment of a suspicious order until they determined, through investigation and due diligence, that the order was not likely to be diverted. The Panel refers to this as the "no-shipping" duty.

8. The Panel holds as a matter of law that the CSA, the WVCSA, and the DEA and Board of Pharmacy regulations have at all relevant times imposed the no-shipping duty, requiring Defendants to stop shipment of a suspicious order until they determined, through investigation and due diligence, that the order was not likely to be diverted. A Defendant's controls against diversion of controlled substances cannot be "effective" if orders the Defendant identifies as suspicious are nonetheless shipped before the Defendant can determine that the orders are not likely to be diverted.

9. The Panel's construction of the CSA is confirmed by Congress itself. On October 24, 2018, Congress enacted Public Law 115-271, the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (the "SUPPORT Act"). As the SUPPORT Act explains, "[t]he purpose of this chapter is to provide drug

manufacturers and distributors with access to anonymized information through [ARCOS] to help drug manufacturers and distributors identify, report, and stop suspicious orders of opioids and reduce diversion rates." PL 115-271, § 3272 (emphasis added). The SUPPORT Act goes further still by providing an express "Rule of Construction" that "[n]othing in this chapter should be construed to absolve a drug manufacturer, drug distributor, or other [DEA] registrant from the responsibility of the manufacturer, distributor, or other registrant to - (1) identify, ***stop***, and report suspicious orders; or (2) maintain effective controls against diversion." Id. (emphasis added).

10. Congress thus made clear that the purpose of this provision of the SUPPORT Act is to give registrants additional tools – in the form of ARCOS data – to carry out their CSA duties, ***including the duty to stop shipments***, and that the provision of these tools (or any previous lack of access to them) does not in any way absolve registrants of their statutory and regulatory duties, again including the existing duty to stop suspicious orders.

11. "Subsequent legislation declaring the intent of an earlier statute is entitled to great weight in statutory construction." *Red Lion Broadcasting Co. v. FCC*, 395 U.S. 367, 380-81 (1969). It is also significant that, in ratifying the DEA's construction of the CSA, Congress did not amend the CSA to impose more explicitly the no-shipping requirement. This Panel can reasonably infer that Congress did not expressly impose this duty because it understood that the duty ***already*** existed under the CSA, and that it was necessary only to make clear how the provisions of the SUPPORT Act might assist registrants in carrying out this duty. *See Heckler v. Turner*, 470 U.S. 184, 211 (1985) (clarification of existing statute in subsequent legislation not only "leaves no doubt as to the prospective interpretation of the statute, but it carries in addition considerable retrospective weight.").

12. The Panel's construction of the DEA's regulations is similarly supported by the views of the DEA itself. *In Southwood Pharmaceuticals, Inc*.; Revocation of Registration, 72 FR 36487-01, 36500, 2007 WL 1886484 (Dep't of Justice July 3, 2007), the DEA found that Southwood had failed to report suspicious orders, that it also had failed to perform proper due diligence with respect to its customers, and that it had continued shipping to certain customers even though their orders met the criteria to be considered "suspicious." 72 FR at 36498-99, 2007 WL 1886484. The DEA found it "especially appalling" that, in light of the information available to it indicating that certain pharmacies to which it was shipping hydrocodone were engaging in diversion, Southwood "did not immediately stop distributing hydrocodone to any of the pharmacies." *Id*. at 36500. The DEA emphasized "the threat to public safety posed by the diversion of controlled substances" and revoked Southwood's license, effective immediately, finding that "continued registration constituted an imminent danger to public health and safety." *Id*. at 36504. Thus, Southwood's violation of the no-shipping duty was a primary reason for revocation of its registration to distribute controlled substances.

13. The DEA further and unequivocally articulated the no-shipping duty in letters it sent to opioid distributors in 2006 and 2007. In a September 27, 2006, letter, the DEA reminded distributors that, "in addition to reporting all suspicious orders, a distributor has a statutory responsibility to exercise due diligence ***to avoid filling suspicious orders*** that might be diverted into other than legitimate medical, scientific, and industrial channels." Letter to Registrants of U.S. Drug Enforcement Administration by Joseph T. Rannazzisi, Deputy Assistant Administrator, Office of Diversion Control, dated September 27, 2006 (Plaintiffs' Mem., Exh. D) (emphasis added). In December 2007, the DEA reminded registrants that:

> their responsibility does not end merely with the filing of a suspicious order report. Registrants must conduct an independent analysis of suspicious orders

> ***prior to completing a sale*** to determine whether the controlled substances are likely to be diverted from legitimate channels.

Letter to Registrants of U.S. Drug Enforcement Administration by Joseph T. Rannazzisi, Deputy Assistant Administrator, Office of Diversion Control, dated December 27, 2007 (Plaintiffs' Mem., Exh. E) (emphasis added).

14. Thomas Prevoznik, the DEA's Rule 30(b)(6) representative, confirmed there was a no-shipping duty – that if a wholesale distributor gets a flag of a suspicious order, that they've determined to be a suspicious order, and they block that shipment, they should terminate all future sales to that same customer until they can rule out that diversion is occurring. (Plaintiffs' Mem., Exh. F).

15. The Panel's construction of the CSA and the DEA's regulations to impose the no-shipping duty is further supported in the decisions of federal and state courts that likewise have adopted this construction. *See In re Nat'l Prescription Opiate Litig*., No. 1:17-md-2804, 2019 WL3917575, at *8-9 (N.D. Ohio Aug. 19, 2019); *Cherokee Nation v. McKesson Corp*., 529 F. Supp. 3d 1225, 1235 (E.D. Okla. 2021); *City of Chicago v. Purdue Pharma L.P.*, No. 14-cv-4361, 2021 WL 1208971, at *7 (N.D. Ill. Mar. 31, 2021); *City & Cnty. of San Francisco v. Purdue Pharma L.P.*, 491 F. Supp. 3d 610, 631-32 (N.D. Cal. 2020); *State of Washington v. McKesson Corp.*, No. 19-2-06975-9 SEA (Wash. Cir. Ct. Sept. 1, 2021) at 3.

16. In particular, the Panel is persuaded by the federal multidistrict litigation (MDL) court's recognition that:

> [G]iven the overriding duty of a registrant to maintain effective controls against diversion, the Court is hard-pressed to think of a more basic requirement than not to ship a dubious order bearing indicia that the drugs could be diverted to illegal channels. How can a registrant freely ship suspicious orders and still comply with its duty to maintain effective controls against diversion? It cannot. It has a duty not to ship the order unless due diligence reasonably dispels the suspicion.

2019 WL 3917575, at *9.

17. Although the Panel denied a similar motion made by the State of West Virginia in its cases against certain manufacturers of prescription opioids in favor of letting the parties present their case, the Panel recognized the logic of Judge Polster in the MDL and Judge Scott in the State of Washington on this issue. *See* March 25, 2022 Pre-Trial H'rg Trans. at p. 47 (Transaction ID 67431745), *In re: Opioid Litigation,* Civil Action No. 21-C-9000 MFR (Kan. Co. Cir. Ct.)(Swope, J.) Now, having the benefit of testimony and other evidence presented in the manufacturers trial, the Panel finds that the evidence supports the finding of a no-shipping duty, as identified by Judge Polster, and adopts the MDL court's analysis of the no-shipping duty.

18. The Panel's construction of the WVCSA to impose the no-shipping duty is supported by the Act's provision establishing that a qualification for controlled substance licensure is that an applicant operates "in compliance with all federal legal requirements applicable to wholesale drug distribution." W. Va. Code § 60A-8-7(c)(1)(I). The Act defines a registered "wholesale drug distributor" to include "any person or entity engaged in wholesale distribution of prescription drugs...." W. Va. Code § 60A-8-5(b). Defendants as distributors of controlled substances, thus are included within the WVCSA's requirement for federal compliance.

19. The Panel's construction of the Board of Pharmacy's regulations to likewise impose the no-shipping duty is supported by the Board's regulation expressly adopting the requirements of the CSA and the DEA's regulations. *See* W. Va. CSR § 15-2-3.1.

20. For all of the foregoing reasons, the Panel holds as a matter of law: (1) that the CSA, WVCSA, and DEA and Board of Pharmacy regulations have at all relevant times required Defendants, as distributors of controlled substances, to maintain effective controls against

diversion; and (2) that in order to meet this obligation, Defendants must (a) design and operate a system to identify suspicious orders; (b) report suspicious orders to the DEA and the West Virginia Board of Pharmacy; and (c) stop shipment of suspicious orders, and hold orders of a similar drug class, pending investigation and due diligence.

ORDER

Based on the foregoing Findings of Fact and Conclusions of Law, *City/County Plaintiffs' Motion for Partial Summary Judgment Regarding Duties Arising Out of the Controlled Substances Act* (Transaction ID 67623039) is **GRANTED**.

Distributor Defendants' objections are noted for the record.

A copy of this Order has this day been electronically served on all counsel of record via File & Serve*Xpress*.

It is so **ORDERED.**

ENTERED: June 8, 2022

/s/ Alan D. Moats
Lead Presiding Judge
Opioid Litigation

/s/ Derek C. Swope
Presiding Judge
Opioid Litigation